EPO - Munich 37
13. Feb. 2006

Notice of Opposition to a European Patent

To the European Patent Office

Tabulation Marks

for EPO use only

I. Patent opposed	Opp. No.	OPPO (1)
Patent No.	1 180 978	
Application No.	00 93 2801.4	
Date of mention of the grant in the European Patent Bulletin (Art. 97(4), 99(1) EPC)	May 11, 2005	
Title of the invention: Apparatus for treating disc herniation		
II. first named in the patent specification	Ferree, Bret A.	
Proprietor of the Patent		
Opponent's or representative's reference (max. 15 spaces)	M 1047 EP/OPP	OREF
III. Opponent	OPPO (2)	
Name	Intrinsic Therapeutics, Inc.	
Address	30 Commerce Way Woburn, MA 01801 U.S.A.	
State of residence or of principle place of business	U.S.A.	
Telephone/Telex/Fax		
Multiple opponents	☐ further opponents see additional sheet	
IV. Authorisation		
1. Representative	OPPO (9)	
(Name only one representative to whom notification is to be made)		
Name	Vossius & Partner	
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Additional representative(s)	☐ (on additional sheet/see authorisation)	OPPO (5)
2. Employee(s) of the opponent authorised for these opposition proceedings under art. 133(3) EPC	Name(s):	
Authorisation(s)	☒ not considered necessary	
To 1./2.	☐ has/have been registered under No.	
	☐ is/are enclosed	

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EPO Form 2300.1

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V. Opposition is filed against

— the patent as a whole ☒

— claim(s) No(s).

VI. Grounds for opposition:

Opposition is based on the following grounds:

(a) the subject-matter of the European patent opposed is not patentable (Art. 100(a) EPC) because:

— it is not new (Art. 52(1); 54 EPC) ☒

— it does not involve an inventive step (Art.52(1); 56 EPC) ☒

— patentability is excluded on other grounds, i.e. Arts. 52(4), 57 EPC ☒

(b) the patent opposed does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Art. 100(b) EPC; see Art. 83 EPC). ☒

(c) the subject-matter of the patent opposed extends beyond the content of the application/ of the earlier application as filed (Art. 100(c) EPC, see Art. 123(2) EPC). ☒

VII. Facts and arguments

(Rule 55(c) EPC)
presented in support of the opposition are submitted herewith on a separate sheet (annex 1) ☒

VIII. Other requests:

As an auxiliary request oral proceedings according to Art. 116 EPC are to be held.

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IX. Evidence presented

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Enclosed = ☒

will be filed at a later date = ☐

A. Publications:	Publication date
1 EP-B-1 180 978 (Patent in Suit) Particular relevance (page, column, line, fig.):	
2 WO 99/061840 Particular relevance (page, column, line, fig.):	
3 US 5,702,454 Particular relevance (page, column, line, fig.):	
4 EP-A-0 700 671 Particular relevance (page, column, line, fig.):	
5 US 5,534,028 Particular relevance (page, column, line, fig.):	
6 US 5,192,326 Particular relevance (page, column, line, fig.):	
7 WO 95/34331 Particular relevance (page, column, line, fig.):	
Continued on additional sheet ☒	

B. Other evidence	
Continued on additional sheet ☐	

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X. Payment of the opposition fee is made

☒ as indicated in the enclosed voucher for payment of fees and costs (EPO Form 1010)

☐

XI. List of documents:

Enclosure No.:			No. of copies
0	☒	Form for notice of opposition	1
1	☒	facts and arguments (see VII.)	1
2		Copies of documents presented as evidence (see IX.)	
2a	☒	— Publications	1
2b	☐	— Other documents	
3	☐	Signed authorisation(s) (see IV.)	
4	☒	Voucher of payment of fees and costs (see X.)	1
5	☐	Cheque	
6	☒	Additional sheet re box IX, A. Publications	1
7	☒	Other (please specify here): Feature Analysis	1

XII. Signature of opponent or representative

Place Munich

Date February 13, 2005

Axel Stellbrink
European Patent Attorney

Please print name under signature. In the case of legal persons, the position which the person signing holds within the company should also be printed.

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00 93 2801.4 / 1 180 978
Patentee: Ferree, Bret A.
Opposition by: Intrinsic Therapeutics, Inc.
Our Ref.: M1047 EP/OPP

Additional sheet re box IX. Evidence presented, A. Publications

8. US 5,846,261

9. US 4,665,906

10. US 5,976,174

11. US 5,690,674

12. US 5,116.357

13. Nucléoplastie Inter-Somatique Par Voie Postérieure Per-Dissectomie : Concept et Étude Expérimentale. J.L.Husson. et al., Restabilisation Inter-Somatique Du Rachis Lombaire, Sauramps Medical, 1996, pp. 311-320.

14. Inter-Somatic Nucleoplasty By Posterior Path During Discectomy: Concept And Experimental Study. J.L.Husson. et al., Inter-Somatic Restabilization Of The Lumbar Spine, Sauramps Medical, 1996, pp. 311-320. English translation of D12a

15. WO 01/10316 (application as published)

16 US 09/322516 (priority document)

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00 93 2801.4 / 1 180 978
Patentee: Ferree, Bret A.
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Facts & Arguments

1. Subject-matter of EP 1 180 978

1.1 Technical Field

European Patent 1 180 978 (further referred to as the "patent", D0) generally relates to prosthetic appliances and, in particular, to devices for occluding intervertebral disc defects and instrumentation associated with introducing such devices (see paragraph [0001]).

1.2 Person Skilled in the Art

The person skilled in the art is considered as being formed by a team of a physician working in the field of prosthetic appliances, and, in particular, in the field of occluding defects, and an engineer having a university degree and experience in the field of medical devices such as devices for occluding defects and instrumentation associated with introducing such devices, and in particular in the field of researching, developing and testing such devices.

1.3 Feature Analysis of the Claimed Subject-Matter

In the following, the content of independent claim 1 will be discussed. A copy of the following feature analysis is also enclosed as **D13**.

Claim 1 according to the Patent as published relates to a device (202) for preventing the escape of natural, artificial, or therapeutic material through a defective region (204) in an annulus fibrosis of a spinal disc, and for preventing disc herniation, said device (202) having

(1) a first physical extent facilitating introduction of the device relative to the defective region (204) in the annulus fibrosis, and

(2) a predetermined second physical extent forming a final shape of the device (202), different from the first,

- preamble -

(3) the device (202) is composed of material that naturally returns to the predetermined second physical extent and

(4) which functions to occlude the defective region (204) by expanding from the first physical extent to the second physical extent,

(5) wherein no further steps are required to form the predetermined second physical extent.

- characterizing clause -

2. Prior Art

In the following, the prior art and documents referred are listed in combination with short-references as used hereinafter:

D0:	EP-B-1 180 978 (Patent in suit)
DI:	WO 99/061840
D2:	US 5,702,454
D3:	EP-A-0 700 671
D4:	US 5,534,028
D5:	US 5,192,326
D6:	WO 95/34331
D7:	US 5,846,261
D8:	US 4,665,906
D9:	US 5,976,174
D10:	US 5,690,674
D11:	US 5,116,357
D12a:	Nucléoplastie Inter-Somatique Par Voie Postérieure Per-Dissectomie : Concept et Étude Expérimentale. J.L.Husson. et al., Restabilisation Inter-Somatique Du Rachis Lombaire, Sauramps Medical, 1996, pp. 311-320.
D12b:	Inter-Somatic Nucleoplasty By Posterior Path During Discectomy: Concept And Experimental Study. J.L.Husson. et al., Inter-Somatic Restabilization Of The Lumbar Spine, Sauramps Medical, 1996, pp. 311-320. English translation of D12a
D13:	Feature Analysis
D14:	WO 01/10316 (application as published)
D15:	US 09/322516 (priority document).

It is further referred to any documents cited in the contested patent or in the search report or referred to during the examination proceedings. Opponent further reserves the right to search for and cite further prior art in case this is deemed expedient in view of patentee's submissions.

3. Inadmissible Broadening – Arts. 100(c) and 123(2) EPC

3.1 Claim 1 extends beyond the content of the application as filed (PCT/US2000/014708, D14) in at least the following respects.

3.1.1 Claim 1 recites that the device has a predetermined second physical extent forming a final shape of the device different from the first (physical extent) (feature (2)).

The only clear and unambiguous disclosure in the application as filed of the device having a predetermined second physical extent is to be found in claim 7 as originally filed, which relates to a device composed of a material that naturally returns to a predetermined second physical extent from a first physical extent that is achieved by straightening the device.

Claim 1 broadens the original disclosure to a second *predetermined* extent derived from *any* first physical extent. There is also no clear and unambiguous disclosure in the application as filed that the predetermined second extent in all the embodiments covered by claim 1 is necessarily the final shape of the device.

In particular, in the Patent numerous different embodiments are discussed, many of which do not support this inadmissible broadening of claim 1. For example, the embodiments shown in, e.g., Fig. 12, 13, 15, 18, 19 and 29 and discussed in the respective passages of the specification do obviously not support the feature that a *predetermined* extent is derived from a first physical extent irrespective of how said first physical extent is achieved.

Therefore, claim 1 violates Art.100(c) EPC.

3.1.2 Claim 1 recites that no further steps are required to form the second physical extent (feature (5)). This is an impermissible disclaimer.

There is no disclosure in the application as filed that all the devices of claim 1 do not require any further steps to form the second physical extent. To the contrary, many of the embodiments discussed in the specification of the Patent seem to require additional steps, such as the collapsed bag that has to be placed into the disc space, then filled with a gas, liquid or gel once in position (see page 17, lines 9 to 11 of **D14**).

In decisions G1/03 and G2/03, the Enlarged Board of Appeal has defined what disclaimers are and those that are admissible or inadmissible.

According to the Enlarged Board of Appeal, a disclaimer is "... an amendment to a claim resulting in the incorporation therein of a "negative" technical feature..." (G1/03 Reasons point 2). "Without requiring any further steps to form the second physical extent" according to feature (5) is clearly a negative technical feature "...excluding from the claim further specific embodiments or areas..." (G1/03 Reasons point 2).

This disclaimer was introduced during prosecution by the patentee in an attempt to distinguish prior art cited by the Examining Division under Art. 54(2) EPC (WO9820939 and US 5,645,597 – see communications dated January 23, 2003 and December 5, 2003).

According to the Enlarged Board of Appeal, a disclaimer may only be allowable to restore novelty by delimiting a claim against anticipation under Art. 54(2) EPC where such anticipation is accidental ie. it is "...so unrelated to and remote from the claimed invention that the person skilled in the art would never have taken it

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into consideration when making the invention..." (G01/03 and G02/03 Order point 2.1).

This prior art cited by the Examining Division relates to defects in spinal discs, the same field as the alleged invention in the opposed patent. Therefore it cannot be said that the skilled person would never have considered this art. Accordingly, the disclaimer is inadmissible.

The opponent notes that removal of this disclaimer will broaden the scope of protection and is therefore not allowed under Art. 123(3) EPC.

4. **Unpatentable Subject-Matter – Art. 100(a) and Arts. 52(4) and 57 EPC**

Claim 1 relates, i.a., to a device that has a first physical extent facilitating introduction of the device relative to a defective region (feature (1)). The device has a predetermined second physical extent forming a final shape of the device (feature (2)). According to feature (5), no further steps are required to form the predetermined second physical extent.

Accordingly, feature (5) teaches that claim 1 relates to method steps for forming a predetermined second physical extent starting from a first physical extent.

Claim 9 teaches to separately introduce a plurality of devices into the human body and thus relates to a method step.

Claim 12 claims a device retained in notches in the vertebrae, i.e., a device being retained in a live person for preventing, i.a., disc herniation.

Since methods for treatment of the human body by surgery practised on the human body are susceptible of industrial application (Art. 52(4), 57 EPC) at least the subject-matter of present claims 1, 9 and 12 relating to the introduction of a device

into the human body and a device being introduced into the human body, respectively, is excluded from patentability.

5. Invalid Priority Claim of EP 1 180 978

5.1 At least the following features of Claim 1 cannot be derived from the priority document (US 09/322516, **D15**).

5.1.1 Claim 1 recites that the device has a predetermined second physical extent forming a final shape of the device different from the first (physical extent) (feature (2)).

There is no clear and unambiguous disclosure in the priority application of the device having a predetermined second physical extent. Neither the term "predetermined" nor an equivalent expression is used in the priority document.

Accordingly, analogous to the above discussion in item 3.1.1, feature (2) has no basis in the priority application.

5.1.2 Claim 1 recites that no further steps are required to form the second physical extent (feature (5)).

There is no disclosure in the priority document that all the devices of claim 1 do not require any further steps to form the second physical extent. To the contrary, many of the embodiments discussed in the specification of the priority document seem to require additional steps. See, e.g., page 8, lines 4 to 11 of the priority application (**D15**) teaching the step of pulling a sheath backwardly or of pushing a rod forwardly in order to achieve a second shape.

Accordingly, analogous to the above discussion in item 3.1.2, feature (5) has no basis in the priority application.

5.1.3 Claim 1 recites that the device has a first physical extent facilitating the introduction of the device relative to the defective region in the annulus fibrosis (feature (1)).

This feature is not derivable from the priority document. In particular, claim 1 of the priority document relates to the device being "introduced into the defective area". According to the priority document, the first shape (first physical extent in the Patent, see below) is such that it permits the device to be introduced into the defective area. However, according to claim 1 of the patent, the first physical extent is such that it facilitates introduction of the device relative to the defective region.

Obviously, a positioning somewhere relative to a specific location is not derivable from a positioning exactly in a specific location.

Moreover, the priority document refers to a first and second shape of the device whereas the Patent makes reference to a first and second physical extent. Obviously, a physical extent is not the same as its shape. For example, two devices of different size may still have the same shape whereas their physical extents differ.

Accordingly, feature (1) has no basis in the priority application.

5.1.4 It is further noted that Figs. 16 to 30 and the respective description (see paragraphs [0029] to [0037] of the patent) have been added when filing the application (D14) underlying the Patent. These Figs. and the respective specification have no basis in the priority document (D15).

5.1.5 Therefore, the opposed Patent does not enjoy the priority date of US 09/322516 (D15).

6. Lack of Novelty – Art. 100(a) and Art. 54 EPC

6.1 Claim 1 vis-a-vis WO 99/61084 (D1)

D1 was filed on May 27, 1999 and claims priority to an application filed May 29, 1998. D1 was published on December 2, 1999. Because the opposed patent is not entitled to its priority date of May 28, 1999, see item 5 above, D1 is full prior art according to Art. 54(2) EPC. In any case, D1 is prior art under Art. 54(3) EPC.

D1 discloses a device for preventing escape of material through a defective region in an annulus fibrosis of a spinal disc and for preventing disc herniation (page 4, lines 8 to 19 and page 8, lines 6 to 12 of D1).

D1 discloses a device that has a first physical extent that facilitates introduction of the device into the disc that is adapted for insertion into an aperture located in the annulus (page 8, lines 6 to 12 of D1), according to feature (1), and which expands from a deformed or constricted state (page 6, lines 15 to 19 of D1) to a final "predetermined shape", according to feature (2) (page 17, line 19 to page 18, line 10 of D1).

The device disclosed in D1 is composed of a material that naturally returns to the predetermined second physical extent, without requiring any further steps to form the second physical extent, as required by features (3) and (5). D1 discloses a device that is able to "conform itself" and is "adapted to provide, or tend toward, a predetermined shape and dimensions" (page 17, line 19 to page 18, line 18 of D1).

D1 discloses a device that occludes the defective region by expanding from the first physical extent to the second physical extent, according to feature (4). The device in D1 comprises a material that is adapted to be sealably positioned within the aperture (page 4, lines 8 to 19 and page 8, lines 6 to 12 of D1) and seals or occludes the annulus "in a manner sufficient to prevent extrusion of the inner

material of the nucleus" (page 8, lines 6 to 12 of **D1**). As indicated above, this is achieved by expansion from the first to the second physical extent.

Accordingly, **D1** discloses each of features (1) to (5) of Claim 1. Thus, Claim 1 is not novel in view of **D1**.

6.2 Claim 1 vis-a-vis US 5,702,454 (D2)

D2 was published on December 30, 1997 and is therefore full prior art according to Art. 54(2) EPC.

D2 discloses a device for preventing the escape of natural and artificial material through a defective region in the annulus fibrosis of a disc, thereby minimizing or preventing a spinal disc herniation.

D2 discloses multiple support members that are inserted through an aperture in the annulus, such that at least one of the support members prevents the escape of the support members through the aperture. **D2** at col. 3, line 29 – col. 3, line 12; col. 5, lines 11-21. **D2** discloses that the support members may replace only a part of the nucleus, thereby teaching that a portion of the natural nucleus pulposus may remain in the disc (col. 3, line 33). Thus, the device of **D2** also serves to prevent the escape of natural material through the defective region..

Devices disclosed in **D2** have a first physical extent that facilitates introduction of the device into the disc (Figure 5) and a second predetermined physical extent forming the final shape of the device (Figure 4e). Accordingly, D2 discloses features (1) and (2) of claim 1.

These devices have elastically deformable expansion elements. To facilitate introduction into the disc, the expansion elements are deformed into a first physical extent when inserted through a delivery tube and, on leaving the tube, spring back to a predetermined final second physical extent, col. 5, lines11-21.

Thus, **D2** discloses a device that naturally returns (by springing back) to a predetermined second physical extent, without requiring any further steps to form the second physical extent, and which functions to occlude the defective region by expanding to the second physical extent, as required by features (3) to (5).

Accordingly, **D2** discloses each of features (1) to (5) of Claim 1. Thus, claim 1 is not novel in view of **D2**.

6.3 Claim 1 vis-a-vis EP 0 700 671 A1 (D3)

D3 was published on March 13, 1996 and is therefore full prior art according to Art. 54(2) EPC.

D3 discloses a device for preventing the escape of natural and artificial material through a defective region in the annulus fibrosis of a disc. **D3** discloses a hydrogel that expands in the disc to prevent the escape of hydrogel (the artificial material) through a window or opening (the defective region) in the annulus. **D3** at col. 11, lines 45-51; col. 12, lines 30-33. Thus, by sealing or occluding the defect in the annulus, the expanded hydrogel device of **D3** prevents the escape of hydrogel through the defect. **D3** discloses that the hydrogel may replace only a part of the nucleus, thereby teaching that a portion of the natural nucleus pulposus may remain in the disc. Thus, the device of **D3** also serves to prevent the escape of natural material through the defective region (col. 12, lines 43-47).

The device disclosed in **D3** has a first physical extent (a dehydrated hydrogel) that facilitates introduction of the device into the disc according to feature (1). **D3** discloses that introducing the device in dehydrated form facilitates introduction by:

> make[ing] it possible to implant the device posterior-laterally during surgery, thereby reducing the complexity and risk of intraspinal surgery as traditionally used. The danger of perforation

of the nerve, dural sac, arteries and other organs is also reduced. In addition, the incision area on the annulus can be reduced, thereby helping to heal the annulus and prevent the rehemiation of the disc. See col. 7, lines 10-19 of D3.

The device disclosed in D3 has a predetermined second physical extent forming the final shape of the device. D3 discloses that the device has shape memory (col. 12, line 22) and that "[a]fter implantation, the hydrogel nucleus of the present invention swells in the body to a predetermined height", according to features (2) and (4), see col. 13, lines 2-5 of D3.

The device disclosed in D3 naturally returns to a predetermined second and final physical extent through expansion, without requiring any further steps to form the second physical extent, as required by features (3) and (5). D3 discloses a dehydrated hydrogel that "return[s] to its original shape upon hydration." col. 7, lines 10-14.

Thus, D3 discloses a device for preventing the escape of artificial material (hydrogel) and natural material (nucleus pulposus) through a defective region in the annulus, wherein the device has a first physical extent (e.g., dehydrated) that facilitates introduction of the device into the disc and which naturally returns to a predetermined second physical extent and by occludes the defective region by expansion (e.g., by swelling or hydration) thereby forming a final shape, without requiring any further steps to form the second physical extent.

Accordingly, D3 discloses each of features (1) to (5) of Claim 1. Thus, claim 1 is not novel in view of D3.

6.4 Claim 1 vis-à-vis US 5,534,028 (D4)

D4 was published on July 9, 1996 and is therefore full prior art according to Art. 54(2) EPC.

D4 discloses a device for preventing the escape of natural and artificial material through a defective region in the annulus fibrosis of a disc. D4 discloses two or more pieces of hydrogel of different stiffness that expand in the disc. D4 at col. 5, lines 36-44. The stiffer piece is placed near the defective region of the annulus (the area where an annulus is weakened due to damage or surgical incision), thereby preventing the escape of hydrogel (the artificial material) through the defective region in the annulus. col. 3, lines 21-24; col. 5, lines 23-44. Thus, by sealing or occluding the defect in the annulus, the expanded hydrogel device of D4 prevents the escape of the softer hydrogel pieces through the defect (col. 8, lines 34-37 of D4). The hydrogel device also prevents the escape of natural material through the defect. D4 discloses that the hydrogel nucleus may replace only a part of the nucleus, thereby teaching that a portion of the natural nucleus pulposus may remain in the disc. Thus, the device of D4 also serves to prevent the escape of natural material through the defective region. (col. 11, lines17-21 of D4).

The device disclosed in D4 has a first physical extent (a dehydrated hydrogel) that facilitates introduction of the device into the disc (feature (1)). D4 discloses that introducing the device in dehydrated form, especially in two pieces; "facilitates implantation, which is done with the hydrogel material in a dehydrated or unhydrated state." (col. 5, lines 36-44 of D4).

The device disclosed in D4 has a predetermined second and final physical extent (feature (2)). D4 discloses hydrogels that are manufactured by forming a mold of the device, wherein the mold (and thus the device) has a "predetermined size and shape." (col. 6, lines 29-41 of D4).

The device disclosed in D4 naturally returns to the second physical extent, without requiring any further steps to form the second physical extent, and occludes the defective region by expansion (features (3) to (5)). According to D4, "[a]fter implantation, the hydrogel nucleus of the present invention swells in the body to a predetermined height" col. 11, lines 34-37.

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Accordingly, D4 discloses each of features (1) to (5) of Claim 1. Thus, claim 1 is not novel in view of D4.

6.5 Claim 1 vis-à-vis US 5,192,326 (D5)

D5 was published on March 9, 1993, and is therefore full prior art according to Art. 54(2) EPC. D5 is mentioned in the specification of the opposed patent.

D5 discloses a device for preventing the escape of natural and artificial material through a defective region in the annulus fibrosis. The device comprises a membrane containing hydrogel in bulk or in beaded form. Once the hydrogel expands, it occludes an opening or defective region in the annulus, thereby preventing the escape of hydrogel (the artificial material) through the defective region, such that "there is no possibility that the hydrogel material can leak out through opening." (col. 13, lines 42-50; (features (2), (4))). Thus, by sealing or occluding the opening in the annulus, the expanded hydrogel device of D5 prevents the escape of hydrogel through the opening. The hydrogel device also prevents the escape of natural material through the defect. D5 discloses that the hydrogel nucleus may replace only a part of the nucleus, thereby teaching that a portion of the natural nucleus pulposus may remain in the disc. Thus, the device of D5 also serves to prevent the escape of natural material through the defective region. (col. 13, lines 56-59 of D5).

The device disclosed in D5 has a first physical extent (a dehydrated hydrogel) that facilitates introduction of the device into the disc (feature (1)). D5 discloses that introducing the device in dehydrated form, especially in the beaded version, facilitates introduction because "[w]hen the hydrogel is dehydrated, its volume will decrease, which makes it possible to implant the prosthetic nucleus through a small window in the annulus or even possibly percutaneously." (col. 8, lines 43-49 of D5).

The device of D5 naturally returns to a predetermined second and final physical extent through expansion, without requiring any further steps to form the second physical extent (feature (2), (3) and (5)). D5 discloses hydrogels that are manufactured by forming a mold of the device, wherein the mold (and thus the device) has a "predetermined size and shape." (col. 11, lines 54-65 of D5). The hydrogel device is then dehydrated to facilitate implantation into the disc. D5 further discloses that "[a]fter implantation, the hydrogel nucleus of the present invention swells in the body to a predetermined height" (col. 14, lines 7-12 of D5). According to D5, the hydrogels in beaded form have excellent visco-elastic properties and shape memory. Thus, the beaded hydrogel returns to a predetermined second and final physical extent through expansion (hydration), without requiring any further steps to form the second physical extent. (col. 7, lines 20-22; col. 11, lines 54-65 of D5)

Accordingly, D5 discloses each of features (1) to (5) of Claim 1. Thus, claim 1 is not novel in view of D5.

6.6 Claim 1 vis-à-vis WO 95/34331 (D6)

D6 was published on December 21, 1995 and is therefore full prior art according to Art. 54(2) EPC.

D6 discloses a plug to occlude an opening in bone to prevent the escape of artificial material (cement) through the opening (D6 at page 1, lines 3-4). Thus, D6 is suitable for minimizing or preventing a spinal disc herniation by preventing the escape of natural, artificial or therapeutic material through a defective region in the annulus fibrosis of a disc.

The device disclosed in D6 has a first physical extent that facilitates introduction of the device into the disc (feature (1)). D6 discloses self-expanding femoral cavity plugs that "are in a compressed form adding to their expandability." (page 8, lines 7-11 of D6). The compressed form can then be delivered in a "tube-in-the-tube"

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introducer to facilitate implantation. (page 8, lines 12-15; page10, lines 15-17 of D6).

The device of D6 naturally returns to a predetermined second physical extent through expansion, without requiring any further steps to form the second physical extent according to features (2) to (5). D6 discloses a device that is made of polymers that "are so-called shape-memory thermoplastics e.g. polyurethane-based softenable shape-memory polymers, which can decrease and/or increase the dimensions when heated from room temperature to body temperature" (page 5, lines 19-22). Thus, D6 discloses a shape-memory plug that returns to its final predetermined shape once it is implanted. According to D6, plug expansion can also result from the substantial absorption of water from tissue fluids resulting in the swelling of the polymeric material (page 4, lines 10-12).

Thus, D6 discloses a device suitable for preventing the escape of material through a defective region in the annulus by occluding the defective region, wherein the device has a first physical extent (e.g., dehydrated, compressed, or unexpanded) that facilitates introduction of the device into the bone and which naturally returns to a predetermined second physical extent through expansion (e.g., through hydration or decompression), thereby forming a final shape, without requiring any further steps to form the second physical extent.

Accordingly, D6 discloses each of features (1) to (5) of Claim 1. Thus, claim 1 is not novel in view of D6.

6.7 Claim 1 vis-à-vis US 5,846,261 (D7)

D7 was published on December 8, 1998 and is therefore full prior art according to Art. 54(2) EPC.

D7 discloses a collapsible medical device for occluding an abnormal opening in a body organ or vessel to prevent the escape of natural material (such as blood)

through the opening. (D7 at col. 1, lines 36-38). Therefore, D7 is suitable for minimizing or preventing a spinal disc herniation by preventing the escape of nucleus pulposus through a defective region in the annulus fibrosis of a disc.

The device disclosed in D7 has a first physical extent that facilitates introduction of the device into the disc (feature (1)). D7 discloses a medical device that is "collapsed into its collapsed configuration and inserted into the lumen of the catheter. The collapsed configuration of the device may be of any shape suitable for easy passage through the lumen of a catheter and proper deployment out the distal end of the catheter." (col. 9, lines 21-39).

The device of D7 naturally returns to a predetermined second physical extent through expansion, without requiring any further steps to form the second physical extent (features (2) to (5)). D7 discloses a device made from a shape memory alloy, NiTi (nitinol). D7 teaches that "NiTi alloys are also very elastic and are said to be 'super elastic' or 'pseudo elastic'. This elasticity allows a device of the invention to return to a preset expanded configuration for deployment." (col. 5, lines 66 to col. 6, lines 15). D7 further discloses that the device will "resiliently return to a preferred expanded shape" and "springs back into this shape" upon implantation. (col. 9, lines 7-10).

Thus, D7 discloses a device suitable for preventing the escape of material through a defective region in the annulus by occluding the defective region, wherein the device has a first physical extent (e.g., collapsed or unexpanded) that facilitates introduction of the device into the desired area, and which naturally returns to a predetermined second physical extent through expansion, thereby forming a final shape, without requiring any further steps to form the second physical extent.

Accordingly, D7 discloses each of features (1) to (5) of Claim 1. Thus, claim 1 is not novel in view of D7.

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6.8 Claim 1 vis-à-vis US 4,665,906, US 5,976,174, US 5,690,674, 5,116,357 (D8 – D11)

D8-D11 disclose devices suitable for preventing the escape of material through a defective region in the annulus by occluding the defective region, wherein the device has a first physical extent (e.g., compressed, collapsed or unexpanded) that facilitates introduction of the device into the desired area, and which naturally returns to a predetermined second physical extent through expansion, thereby forming a final shape, without requiring any further steps to form the second physical extent. Thus, references D8-D11 each anticipate Claim 1.

D8 was published on May 19, 1997 and is therefore full prior art. D8 discloses a variety of compressible or collapsible medical devices that are made from shape memory alloys and used to occlude openings in various body regions.

D9 was filed on December 15, 1997 and was published on November 2, 1999 which is before the filing date of the contested Patent. Since the priority claim of the Patent is invalid, D9 is full prior art. D9 discloses a compressible or collapsible medical device that is made from shape memory alloys and used to seal holes in body tissue, such as septal defects in the heart.

D10 issued on November 25, 1997, and is thus full prior art. D10 discloses a compressible elastic plug to close wounds.

D11 was published on May 26, 1992 and is thus full prior art. D11 discloses a compressible plug to repair hernias by closing openings in the abdominal wall.

The devices of D8-D11 have a first physical extent adapted for facile introduction to the defect, and return to a predetermined second physical extent through expansion, without requiring any further steps to form the second and final physical extent. The devices of D8-D11 are suitable for minimizing or preventing

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a spinal disc herniation by preventing the escape of nucleus pulposus through a defective region in the annulus fibrosis of a disc.

6.9 Claim 1 vis-à-vis (D12)

Document D12 was published in 1996 and is therefore full prior art according to Art. 54(2) EPC.

D12 discloses a device for preventing the escape of natural and artificial material through a defective region in the disc annulus. D12 discloses a shape memory coiling helix that has a first unexpanded physical extent that facilitates introduction of the device into the annulus opening and is compressed for insertion into a small opening in the annulus.

The device has a predetermined second physical extent forming a final shape of the device, because it is made from a shape memory alloy. The device of D12 naturally returns to the predetermined second extent through expansion, without requiring any further steps to form the second physical extent, and functions to occlude the defective region to prevent the escape of the device through the annulus opening. The device also prevents the escape of natural material through the defect in the situation where a portion of the natural nucleus remains in the disc.

Accordingly, D12 discloses each of features (1) to (5) of Claim 1. Thus, Claim 1 not novel in view of D12.

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7. **Lack of Inventive Step – Art. 100(a) and Art. 56 EPC**

As an auxiliary measure, in case the Opposition Division does not follow the argumentation as provided above with regard to inadmissible broadening, unpatentable subject-matter, and lack of novelty, arguments are provided hereinafter regarding lack of inventive step.

In this context it is particularly referred to documents **D6** to **D11** relating to various different devices for the occlusion of openings and defects in the human body. It is obvious for the person skilled in the art starting from any one of **D1** to **D5** or **D12** and being confronted with a problem in the field of the prevention of the escape of natural, artificial, or therapeutic material through a defective region in an annulus fibrosis of a spinal disc, and of the prevention of disc herniation to consider any one of the occlusion devices discussed in **D6** to **D11** which teach all the structural features of claim 1.

In analogy to the above discussion of novelty, the person skilled in the art will directly and unambiguously arrive at the subject-matter of the claim 1 when combining any one of **D1** to **D5** or **D12** with any one of document **D6** to **D11.**

8. **Lack of patentability of the dependent claims**

Dependent claims 2 to 12 do not comprise any additional patentable subject-matter. As is readily apparent from the above discussion of novelty, the subject-matter of the dependent claims lacks novelty in view of the disclosure of documents **D1** to **D12**. Moreover, the subject-matter of the dependent claims has no inventive merits.

9. **Lack of Enablement – Art. 100(b) and Art. 83 EPC**

The Patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Claim 1 requires that a device according to the alleged invention has a first physical extent and a predetermined second physical extent, wherein no further steps are required to form the predetermined second physical extent.

From the claims, however, it is not derivable how to achieve a first and a predetermined second physical extent, particularly without any further steps required. Even the description does not provide a sufficiently clear and complete teaching to carry out the features of the claim. In particular, in the specification of the Patent various embodiments of the alleged invention are discussed which are supposed to be covered by present claim 1, however, the embodiments shown in, e.g., Fig. 12, 13, 15, 18 to 26, 29 and 30 and discussed in the respective passages of the specification do obviously not have a predetermined second physical extent or require different steps for achieving such predetermined second physical extent (see, e.g., col. 11, lines 11-15 and 45-47 of the Patent).

Accordingly, the person skilled in the art is not put in the position of being able to carry out the invention in all its essential aspects and of knowing when he is working within the forbidden area of the claims (see T 0256/87, Reasons for the decision No. 17).

Thus, the Patent is to be revoked in accordance with Article 100(b) EPC.

10. Conclusion

The above comments demonstrate that neither claim 1 nor the dependent claims are patentable. Therefore, the request to revoke the patent in its entirety is justified.

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